Nucletron

K061354

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

AUG 17 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
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Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	MicroSelectron V3
Common/Usual Name:	Afterloader
Classification Name:	Remote controlled radionuclide applicator system
Classification:	21Cfr892.5700 Class II
Product Code	JAQ

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	MicroSelectron PDR	K041933

Description:
The MicroSelectron V3 delivers a radiation dose distribution conforming to treatment data, which is either, manually entered at the workstation or imported from a treatment planning system.

For a treatment, a source and applicator are minimally required. Treatment can be administered via up to 30 applicators connected to 30 channels in the treatment unit. The dose distributions are achieved by sequentially letting the source dwell in required positions within the applicators.

A channel has 48 possible dwell positions. Each position has a number, whereby position 1 represents the farthest possible (distal) position from the treatment unit and 48 the closest (proximal) position. The step size, which is the minimum distance between the centres of consecutive dwell positions, can be set to 2.5 mm, 5 mm, or 10 mm. All channels that are used for a given treatment have the same step size. Treatment in a channel starts at the proximal programmed dwell position. When the dwell time in the proximal position has elapsed, treatment continues in the next programmed dwell position and so on until the last dwell position has been completed; whereupon, the procedure is repeated in the next programmed channel (if applicable).

The required dose distribution can be delivered according to two principles:

- **The "high dose rate brachytherapy"principle (HDR),** i.e. only one treatment cycle as described above is given during a treatment session. The treatment is completed when the last programmed channel is completed.
- **The "pulsed dose rate brachytherapy" principle (PDR),** i.e. treatment cycles (pulses) are given at regular intervals (periods). A pulse includes treatment in a number of channels (determined by the user) depending on the type of application. After having delivered one pulse, the system enters a quiescent state, the duration of which is equal to the period time minus the pulse time. The period time is the elapsed time between two consecutive pulses. The second pulse starts at the end of the first period time. The whole sequence as described above for the first pulse will then be repeated. The treatment is completed when the last pulse has been delivered.

The MicroSelectron V3 consists of the following main components:

- **Treatment Unit (TU)**
  The Treatment Unit contains:
  - Safe for the source
  - Dual drive mechanisms with two stepper motors
  - Position encoders for the source assembly and the check cable, respectively
  - Channel indexer
  - An electrical adjustment for the height of the treatment head
  - Electronic control circuit boards
  - Battery pack and the power supply

- **Treatment Control Panel (TCP)**
  The Treatment Control Panel (TCP) transfers treatment data from the treatment control station to the treatment unit. After the Start button is pressed at the TCP, the treatment unit will execute treatment according to this data. The TCP monitors a treatment by exchanging status messages with the treatment unit and treatment control station.

- **Treatment Control Station (TCS)**
  The Treatment Control Station is a computer with a monitor and a keyboard for user programmable functions, data entry, and detailed operational information.
  Once the Treatment Control Station is activated, and before any radiation treatment can be initiated, the system performs a self-test of all components which relate to safe operation. This diagnostic program checks the system connections, memory status, backup battery status, indexer status, Control Panel indicators, internal clock and audible alarm.
  For data integrity and security the system allows the definition of multiple types of users with different levels of authorization. This authorization is linked to the users password for the Treatment Control Station.
  Patient and treatment data as well as applicator data is stored in the database at the treatment control station. The database stores information of treatment sessions (fractions or pulses) given a course of treatment.

- **Remote Control Unit (RCU)** (optional for HDR)
  The Remote Control Unit (RCU) is mounted outside the treatment room. After preparing a patient and programming the system, treatment can be started. Treatment can be interrupted and later resumed so that a nurse or physician can enter the treatment room and administer care to the patient. The unit also provides information about the treatment and system status.

- **Nurse Station Display** (Optional)
  The Nurse Station Display (NSD) gives staff members the possibility to remotely monitor the treatment and system status. After selecting one of up to four treatment units, the information of the selected treatment unit is shown. The nurse station display works in the same way as the remote control unit for the treatment information, error information, settings, and audible alarm.

The radiotherapy treatment planning software is not part of this 510(k) submission. Applicators and Transfer Tubes as available for microSelectron-HDR/PDR (k953946 & k041933) are also applicable for the microSelectron V3 System.

The modifications to the previously cleared device K041933 are:
- Addition of HDR functionality, part of previously cleared device K902533
- Increase of the number of channels of the indexer from 18 to 30.
- Addition of DICOM import and export functionality
- Increase of maximum source strength for treatment of patients from 40.000 µGy.m²/h (10Ci) to 48.000 µGy.m²/h (12Ci)

Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

The MicroSelectron V3 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular and Intra-operative) or to the surface of the body for radiation therapy.

Summary of technological considerations:

MicroSelectron V3 is substantially equivalent to the cleared predicate device, microSelectron PDR, 510(k)#: K041933.

3 April 2006
Date

Name: Dick van Waes
Title: Business Director Brachytherapy & Imaging
Nucletron B.V.
Veenendaal, The Netherlands

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 17 2006

Ms. Lisa Dimmick
Director Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K061354
Trade/Device Name: MicroSelectron V3
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: July 17, 2006
Received: July 19, 2006

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K061354
Device Name	MicroSelectron V3
Indications for Use	The MicroSelectron V3 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular and Intra-operative) or to the surface of the body for radiation therapy.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061354